

REMARKS

This is in full and timely response to the above-identified Office Action. The above listing of the claims supersedes any previous listing. Favorable reexamination and reconsideration are respectfully requested in view of the preceding amendments and the following remarks.

Claim amendments/Status

In this response the claims have been reviewed and amended to improve syntax, form and to clarify the subject matter for which patent protection is sought. These amendments are deemed to at least overcome the objections and rejections under 35 USC § 112 second paragraph. Non-elected claims 33-53 have been canceled.

Rejections under 35 USC § 102

The rejection of claims 1, 2, 4-9, 12, 13, 16-20, 23-26, 28 and 29 under 35 USC § 102(b) as being anticipated by Chandler, is respectfully traversed.

In this response, claim 1 has been amended to call for:

*at least one detachable chamber which is
filled with a reactant and sealed, the
detachable chamber being selectively
connectable to the channel prior to use.*

The detachable chamber is formed as a separate cartridge which is sealed and which may be plugged into place prior to use for connection with a channel. These features are shown in Fig. 4, 5, and 6, and are described in paragraphs 38, 39, 40, 42, 94, 121, 123 and 124 of the published application.

Neither the Chandler reference nor any of the other citations suggest a sealed separate chamber filled with the reactant and being selectively connectable to the channel prior to use. To the contrary, the references cited, all comprise chambers that are

permanently coupled and integral with the device in question. These requirements are deemed to distinguish the claimed subject matter over the disclosure of Chandler and to moot the anticipation rejection.

The provision of a detachable chamber being selectively connectable to the channel prior to use offers significant advantages compared to permanently integrated chambers. For example, it provides the advantage that reagents can be stored separately. That is to say, reagents which are volatile or degradable can be stored at a lower temperature, while other less sensitive reagents can be stored at room temperature. In addition, it is possible to prepare a reagent such as, an enzyme solution immediately prior to use of the device and load a chamber with this freshly prepared reagent.

The feature that the detachable chamber is sealed prevents any liquid agent contained in the detachable chamber from being discharged or becoming contaminated before use. The seal is removed either immediately prior to connecting the detachable chamber with the channel or upon engaging the connecting means provided on the detachable chamber and on the channel. Such a seal can take on any number of forms known in the art and can be made of a large variety of different materials including but not limited to metal foil, e.g. aluminum foil, metal plated polymer foil, the material of the chamber, a glass bead and a polymer membrane e.g. made of polypropylene or polyethylene.

In this manner an improved device for contamination free preparation of analyte containing sample solution is provided which is not disclosed or suggested by the prior art.

Rejections under 35 USC § 103

1) The rejection of claims 3, 10 and 11 under 35 USC § 103(a) as being unpatentable over Chandler is respectfully traversed.

With regards to claim 3, the rejection asserts that Chandler does not teach a device wherein no means of flow regulation is provided between the first and second chamber. However, it must be pointed out that a number of the chambers in Chandler are provided with conical plugs 30 which are clearly intended to restrict fluid flow under given conditions. Therefore, it cannot be said that there is clear suggestion that it is advantageous to remove a means of flow regulation between the first and second chamber as a means of allowing a reagents to flow freely between the two chambers. Besides, without a full working knowledge of the claimed subject matter and unfettered access to the anticipation rejection, no-one would know which chambers were actually intended to be the first and second chambers.

Thus, while the MPEP may state that it is obvious to omit an element where the function of said element is not desired or required (MPEP 2144.04 II A), in this situation, the use of a plurality of conical plugs clearly suggests that flow resistance is desired. Accordingly, a *prima facie* case of obvious cannot be established.

In addition, Chandler discloses an arrangement comprising a series of barrel-like chambers which are unitarily formed into a single unit. There is no suggestion of a separate detachable unit which can be selectively connected/disconnected at will. This not only distinguishes over the Chandler reference in terms of anticipation but also in terms of obviousness. There is nothing to suggest that at least one of the chambers be arranged in the manner now required by claim 1.

In connection with claim 10, for example, it pure speculation that at least one channel between two of the detachable chambers has a volume larger than the total compressible volume of the system. The disclosure which would lead the hypothetical person of ordinary skill to this conclusion cannot be found by the

Applicant and it is submitted that it is more innovative than is permitted under the § 103 statute, to assume that a channel would be so configured to meet the requirements of claim 10.

As to claim 11, providing at least one of the chambers with a tapered portion would seem to fly in the face of the arrangement disclosed in Chandler wherein the pistons are arranged to travel to the very ends of the chambers. This is something that would be severely inhibited with the conical configuration alleged to be obvious in this rejection.

Again a *prima facie* case of obviousness is not established.

2) The rejection of claims 14 and 15 under 35 USC § 103(a) as being unpatentable over Chandler in view of Kimura is respectfully traversed.

Kimura teaches a reaction vessel wherein the pistons are composed of an elastic material (column 2 lines 42-52). Kimura is cited to teach that it is advantageous to form the piston from an elastic material as a means of preventing evaporation by forming a seal between the piston and vessel wall. Based on this, it is alleged that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Chandler in view of Kimura to utilize a piston composed of an elastic material in order to prevent evaporation of reagents within a chamber as taught by Kimura.

However, in Kimura, the need for the flexibility comes in the need for the piston to be able to enter into a tapered end portion of the vessel body. Inasmuch as there are no such tapered portions in Chandler, it is not seen that the hypothetical person of ordinary skill would consider the allegedly transfer of teachings.

Indeed, in order to establish a *prima facie* case of obviousness, it is necessary to show that the hypothetical person

of ordinary skill would, without any knowledge of the claimed subject matter and without any inventive activity, be provided with disclosure of all of the claimed elements and then motivated to arrive at the claimed subject matter given the guidance of the cited references when each is fully considered as statutorily required. It is submitted that the examiner has failed to meet these requirements in this case.

3) The rejection of claims 21, 22 and 27 under 35 USC § 103(a) as being unpatentable over Chandler in view of Schnipelsky et al., is respectfully traversed.

In this rejection, it is acknowledged that Chandler does not teach magnetic particles within the chambers and/or the channels. To overcome this admitted shortcoming, the Examiner cites Schnipelsky et al., as teaching a containment cuvette wherein magnetic particles are utilized for binding reaction products (column 17 lines 4-17). The rejection goes on to acknowledge that Schnipelsky et al., does not, in fact, teach a specific diameter range for the magnetic beads. To overcome this, the rejection asserts that magnetic beads with small diameters are well known.

The Applicant seasonably calls for the citation of a reference to evidence such as fact in accordance with MPEP 2144.03. Nevertheless, this does not overcome the shortcoming that claim 1, as amended, calls for a structure which a combination of Chandler and Schnipelsky et al., do not resolve.

4) The rejections of claims 30 and 31 under 35 USC § 103(a) as being unpatentable over Chandler in view of Holtzman (US 4,889,692), is respectfully traversed.

Holtzman is cited to teach a disposable sample preparation chamber wherein the chambers have open ends towards the edge of

the chamber. Holtzman is also cited as teaching that the enclosure is attached to a rotatable valve device to allow automatic changing of volume of at least one chamber.

However, Chandler already has such a structure and unlike Chandler, the Holtzman arrangement is not intended to receive volume controlling pistons therein.

Indeed, it is not seen that there is anything that can be gleaned from Holtzman that could be readily transferred to Chandler. Clearly, Holtzman needs be arranged in a cylindrical pattern so as to allow for the rotatable valve member at the bottom of the device to be rotated to permit the various mixing interconnections between the chambers to be established. This is not needed in Chandler and definitely would interfere with the operation of the conical plugs 30 which are clearly required as functioning elements of the arrangement.

Again a *prima facie* case of obviousness cannot be seen as being established.

Conclusion

The claims as amended above, are deemed to be patentable over the cited art for at least the reasons advanced above.

Favorable reconsideration and allowance of this application are courteously solicited.

One month extension of time is hereby requested. A credit card authorization form in the amount of \$65.00 is attached herewith for the one month extension of time.

Respectfully submitted,

HAUPTMAN KANESAKA BERNER

A handwritten signature in cursive script, appearing to read 'Manabu Kanesaka', written in dark ink.

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